UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,596	03/10/2004	Paul D. Mannheimer	009103-016220US	6350

20350 7590 06/03/2005	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP	KREMER, MATTHEW J	
TWO EMBARCADERO CENTER		
EIGHTH FLOOR	ART UNIT	PAPER NUMBER
SAN FRANCISCO, CA 94111-3834	3736	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

	Application No.	Applicant(s)
Office Action Summary	10/798,596	MANNHEIMER ET AL.
	Examiner	Art Unit	
	Matthew J. Kremer	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2005*.

2a)☒ This action is **FINAL.** 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
   closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-12* is/are pending in the application.

   4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

   Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

   Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   a)☐ All b)☐ Some * c)☐ None of:

   1.☐ Certified copies of the priority documents have been received.

   2.☐ Certified copies of the priority documents have been received in Application No. _____.

   3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
      application from the International Bureau (PCT Rule 17.2(a)).

   * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2.   Claims 1-5 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated

by U.S. Patent 4,942,877 to Sakai et al. (Sakai). Sakai teaches a light emitter 20, a

detector 25, and a memory 56. (Fig. 1 of Sakai). Claims 1-5 and 11-12 recite limitations

that attempt to claim particular data that is stored in the memory. A memory only stores

data in the forms of 1's and 0's and such data are not structurally distinct from any other

data that are stored as 1's and 0's. It is the connection to microprocessors that provide

meaning to the data in the memory. Without this connection to provide meaning to the

data, there is not structural distinction from one data set to another.

Claim Rejections - 35 USC § 103

3.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4.   Claims 1-4, 6-7, 9, and 11-12 are rejected under 35 U.S.C. 103(a) as being

unpatentable over U.S. Patent 4,623,248 to Sperinde (cited by Applicant) in view of U.S.

Patent 4,942,877 to Sakai et al. (Sakai)(cited by Applicant). Sperinde discloses an

oximeter in which the oxygen saturation level is computed by using a formula which

uses the ratio of one pair of intensity signals when the oxygen saturation level is

relatively low and with another formula which uses the ratio of another pair of intensity

signals when the oxygen saturation level is relatively high. (Abstract of Sperinde). Each

formula has a different set of coefficients. Sperinde does not disclose a sensor

memory, which stores the coefficients and thresholds for use in the formulas. However,

the method of Sperinde requires the calibrated coefficients and data (including

thresholds) to be stored in a memory to carry its steps since the coefficients need to be

recalled for various different measurements over time. Sakai discloses a memory used

to store coefficients and calibration data (including thresholds) for the determination of

oxygen saturation. The memory is located in the sensor unit. (column 12, lines 6-37 of

Sakai). Such a memory would fulfill the requirement of the necessary storage of the

coefficients and calibration data (including thresholds) in the invention of Sperinde.

Therefore, it would have been obvious to one having ordinary skill in the art at the time

the invention was made to use the memory of Sakai in the invention of Sperinde since

the invention of Sperinde requires a device for data storage of the coefficients and

calibration data and Sakai et teaches one such method. In regard to claim 1, Sperinde

teaches a light emitter and light detector. (Fig. 4 of Sperinde). In regard to claims 2 and

7, the coefficients are based on experiments using specific wavelengths. In regard to

claims 3 and 6, Sperinde discloses a threshold point in the form of saturation values for

determining which of the two formulas to use. (column 5, line 46 to column 6, line 7 of

Sperinde). In regard to claims 4 and 9, the combination also teaches the use of a non-

linear formula. (Fig. 5A of Sperinde).

5.   Claims 1-3, 5-7, and 10-11 are rejected under 35 U.S.C. 103(a) as being

unpatentable over U.S. Patent 4,086,915 to Kofsky et al. (cited by Applicant) in view of

U.S. Patent 4,942,877 to Sakai et al. (cited by Applicant). Kofsky et al. teaches an

oximeter with multiple sets of coefficients for use in calculating oxygen saturation

depending on the range of total hemoglobin concentration. (column 8, lines 8-24 of

Kofsky et al.). The different hemoglobin concentrations would cause different saturation

readings for a particular set of coefficients. Kofsky et al. does not teach that the

coefficients are stored in the sensor. It is well known in the art to use memories in

sensors to store coefficients and calibration data (including thresholds). (column 12,

lines 6-37 of Sakai et al.). Placing sensor-specific threshold values in the memory of a

particular sensor would allow more accurate calculations while removing the need to

store the calibration values in the oximeter for a plurality of different sensors, i.e.,

different sensors can then be used with the oximeter. Further, Sakai et al. suggests that

the coefficients and calibration data (including thresholds) used in calculating oxygen

saturation can be stored in either the sensor or in the main unit. (column 12, lines 6-37

of Sakai et al.). This suggestion implies that placing the calibrated coefficients and data

in the sensor memory is functionally equivalent to placing the calibrated coefficients in

the memory of the main unit.   Therefore, it would have been obvious to one having

ordinary skill in the art at the time the invention was made to modify the sensor of

Kofsky et al. to include a memory in the sensor as disclosed by Sakai et al. since

sensor-specific calibration values in the memory of a particular sensor would allow more

accurate calculations while removing the need to store the threshold value in the

oximeter for a plurality of sensors and Sakai implies that using a memory in the sensor

is functionally equivalent to using a memory in the main unit. In regard to claim 1, the

combination teaches a light source 1, a light detector 9 (Fig. 1 of Kofsky), a memory

(column 12, lines 6-37 of Sakai et al.), and storing multiple sets of coefficients for use in

calculating oxygen saturation depending on the range of total hemoglobin

concentration. (column 8, lines 8-24 of Kofsky et al.). The selection of the coefficients

depends upon the values obtained from the light detector 9. In regard to claims 5-6 and

10, the combination teaches a plurality of coefficients P_i and provides an example of

four sets. (column 8, lines 8-24 of Kofsky et al.).

Double Patenting

6.   The nonstatutory double patenting rejection is based on a judicially created
doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the
unjustified or improper timewise extension of the "right to exclude" granted by a patent
and to prevent possible harassment by multiple assignees. See In re Goodman, 11
F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225
USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA
1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, In re Thorington,
418 F.2d 528, 163 USPQ 644 (CCPA 1969).
     A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be
used to overcome an actual or provisional rejection based on a nonstatutory double
patenting ground provided the conflicting application or patent is shown to be commonly
owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7.   Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,801,797 to Mannheimer et al. (Mannheimer). Although the conflicting claims are not identical, they are not patentably distinct from each other. In regard to claim 11 of the present application, claim 8 of Mannheimer claims an oximeter system comprising "an oximeter sensor comprising a light emitter for directing light at a patient; a light detector mounted to receive light from said patient; and a memory storing a plurality of alternate values of oxygen saturation or signal ratiometric values used to determine oxygen saturation, said plurality of values being dependent on <u>a mean wavelength of said light emitter</u>", which is narrower in scope than claim 11 of the present application. Also, claim 8 of Mannheimer claims a single light emitter, which means there is a single mean wavelength of the emitter. This single emitter means that the plurality of values are dependent upon the same emitter and the same mean wavelength. Claim 8 of Mannheimer meets all the limitations set out in claim 11 of the present application and it would be obvious that the sensor of claim 11 of the present application is actually the sensor of claim 8 of Mannheimer.

Response to Arguments

8.   Applicant's arguments filed 3/31/2005 have been fully considered but they are not persuasive.

In regard to the Sakai rejections, the Applicant asserts that claims 1-5 and 11-12 have been amended to clarify and provide meaning. The Examiner respectfully disagrees. As stated in the rejections above and in the Office Action mailed on 12/28/2004, a memory only stores data in the forms of 1's and 0's and such data are not structurally distinct from any other data that are stored as 1's and 0's. It is the connection to microprocessors with particular programming that provide meaning to the data in the memory but the Applicant merely claims the subcombination of the sensor. Without this connection to provide meaning to the data, there is not structural distinction from one data set to another. The Applicant attempted to provide even more particulars about the memory data but structurally this is still just 1's and 0's. The memory of Sakai is <u>capable for storing any kind of data</u>. The 1's and 0's stored in the memory of Sakai is not structurally distinct from the 1's and 0's of the Applicant's data.

In regard to the Sperinde/Sakai rejection, the Applicant asserts that Sperinde does not teach using different formulas for the same sensor element or light emitter, as claimed in the present application. The Applicant wishes to distinguish between Sperinde's use of Equation (1), which uses wavelengths 2 and 3, and Equation (5), which used wavelengths 1, 2, and 3. The use of wavelength 1 in one of the formulas is irrelevant to the fact that the same wavelength (2 or 3) is used in two different formulas. The claim language does not preclude the use of an additional wavelength (1) in one of the two formulas.

In regard to the Sperinde/Sakai rejection, the Applicant asserts that neither Sperinde nor Sakai disclose or suggest the breakpoint now set forth in claim 6, as

amended. The Examiner respectfully disagrees since a breakpoint of 60% is stored along with the coefficients since those coefficients are a function of that breakpoint. (column 5, line 46 to column 6, line 7 of Sperinde).

In regard to Kofsky/Sakai, the Applicant asserts that Sakai and Kofsky do not show or suggest storing different sets of coefficients or different formulas for the same wavelength of the same light emitter in a sensor memory. The Examiner respectfully disagrees since Kofsky teach the use of the same two wavelengths in the various formulas. (for example, column 7, lines 15-65 and column 8, lines 10-25 of Kofsky). Next, the Applicant asserts that it would not be obvious to combine Sakai and Kofsky to achieve the present invention, as now claimed in claims 1 and 11. The Examiner respectfully disagrees since the Examiner has provided the necessary motivations found in the references themselves in the above rejection. Next, the Applicant asserts that neither Kofsky nor Sakai disclose or suggest the breakpoint now set forth in claim 6, as amended. The Examiner respectfully disagrees since sets of coefficients for the various hemoglobin concentrations inherently include the thresholds because each of the hemoglobin concentrations are the thresholds.

Conclusion

9.   Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Matthew J. Kremer whose telephone number is 571-

272-4727. The examiner can normally be reached on Mon. through Fri. between 8:30
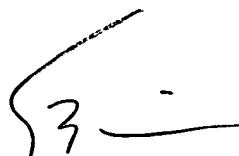
a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number

for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Matthew Kremer
Assistant Examiner
Art Unit 3736

ERIC F. WINAKUR
PRIMARY EXAMINER